TN Department of Health

Impact of "TN Together" Legislation

2021 Report to the 112th Tennessee General Assembly

Tennessee Department of Health| Health Licensure & Regulation | November 1, 2021

Contents

Introduction

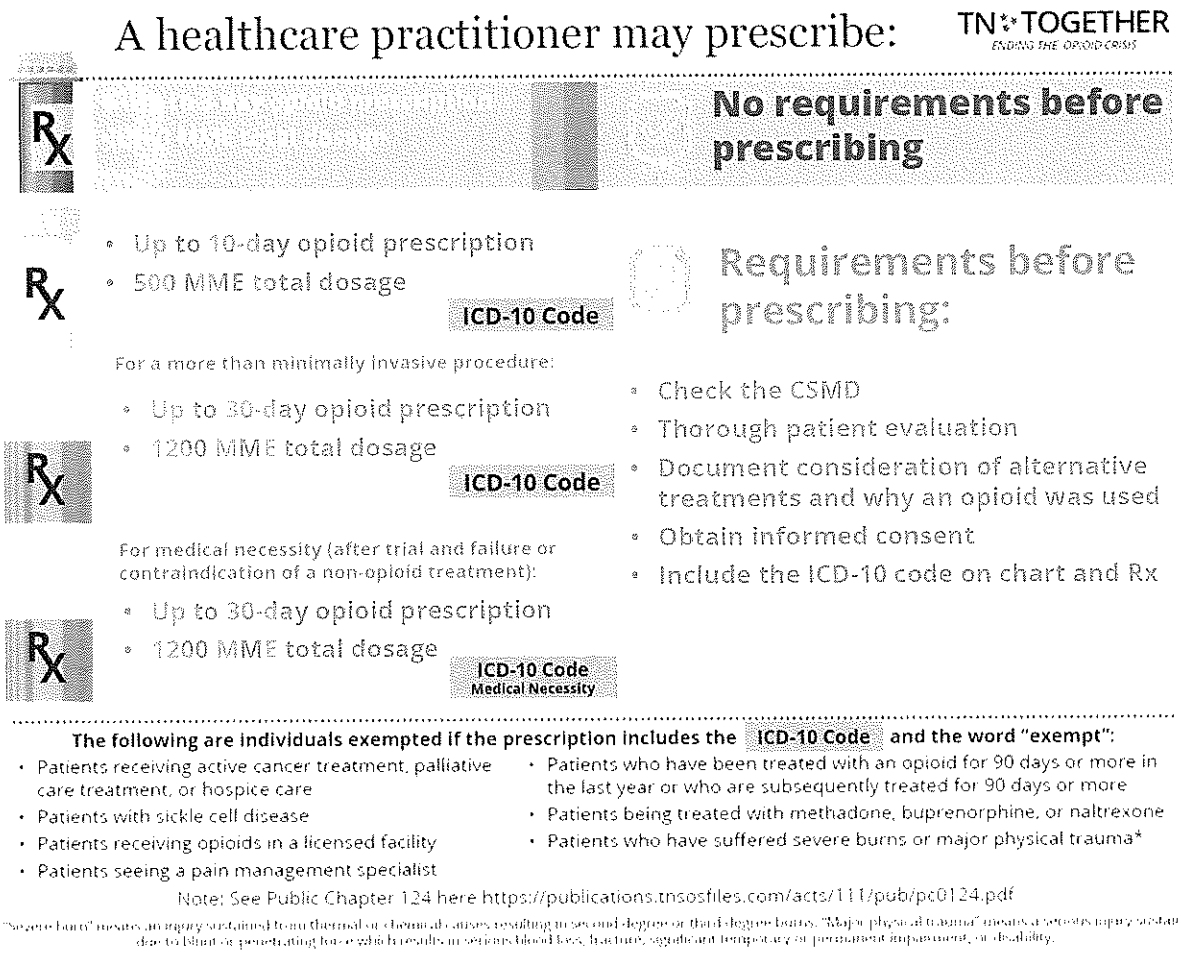
In July 2018, the General Assembly enacted Tenn. Code Ann. § 63-1-164, known as "TN Together" which placed reasonable limits on the amount and duration of opioids used for acute pain. It limits opioid prescriptions to up to a three-day supply with a total of 180 Morphine Milligram Equivalents (MME). Clinical judgement and the patient- prescriber relationship was preserved by providing several exceptions under certain circumstances. Some of the exemptions include patients seeing a pain management specialist, patients receiving active cancer treatment, patients who are undergoing palliative care treatment, patients receiving hospice care, patients with a diagnosis of sickle cell disease, and patients receiving opioids in a licensed facility.

In 2019, the legislature made a variety of changes to the TN Together opioid initiative. Among the changes were the inclusion of definitions for the terms: palliative care, severe burn, and major physical trauma. Palliative care was added as exception to the opioid dosage limits otherwise required under TN Together. The new legislation also made partial filling of opioids permissive. Finally, the opioid limits from the original act were simplified. Instances such as more than minimally invasive surgery, which previously fell under a twenty-day provision, were changed to be treated under the limits of the thirty-day category.

Background and Rationale

In 2018, the Tennessee state legislature passed a suite of new laws aimed at curbing initial opioid prescriptions for opioid-naïve patients with the intent of combatting the opioid overdose epidemic. A portion of those laws, now codified as Tenn. Code Ann. § 63-1-164, established limits to initial opioid prescriptions for most Tennesseans as well as exemptions for chronic pain and other medical necessities. As the TN Together infographic shows Figure 1), initial prescriptions of no more than three days and no more than 180 Morphine Milligram Equivalents (MME, a measure that standardizes the dose of various types of opioid medications) could be written without a medical exemption. Longer prescriptions with higher total MME could be written if they met certain requirements and included an indication of the patient's medical needs through the use of an International Classification of Diseases, Tenth Revision, Clinical Modification code (typically abbreviated ICD-10-CM, but hereafter referred to as an ICD-10 code).

Figure 1



Exemptions exist for methadone, buprenorphine, or naltrexone, which are for the treatment of opioid use disorder only.

Source: https://www.tn.gov/opioids/education-and-prevention/laws-and-policies.html

Additional exemptions exist. There is no MME limitation for patients undergoing cancer treatment or palliative care, receiving hospice care, diagnosed with sickle cell disease, to whom opioids are administered in a hospital, or who are severe burn or major physical trauma victims. Further exemptions exist for patients who were already treated with an opioid for ninety (90) or more days during the last year, and for all prescriptions written by pain management specialists or by a provider in a hospital-based pain management clinic. Exemptions also cover patients receiving treatment for opioid abuse disorder.

Tenn. Code Ann. § 63-1-164(f) directed the Tennessee Department of Health (TDH) to "study and analyze the impact and effects of the restrictions and limitations" created by this law. To respond to this requirement, a workgroup was convened at TDH that included members of the Division of Health Licensure and Regulation, the Office of General Counsel, the senior leadership team, and analysts in the Office of Informatics and Analytics. After reviewing existing data on prescribing patterns in the state, the workgroup devised a set of questions to guide the analyses to be included in the report.

The five key questions that came out of this workgroup were:

1) What impacts did the prescribing limitations imposed by Tenn. Code Ann. § 63-1-164 have on the days' supply and Morphine Milligram Equivalents of opioid prescriptions written after the law's implementation?

2) How did long-term opioid use change for opioid-naïve/non-exempt patients?

3) Did prescribing patterns change for the population of chronic opioid patients who were specifically carved out by the law?

4) What types of justifications were recorded for prescriptions that were reported as exempt?

5) What changes were observed in overdose deaths involving prescription opioids before and after the law's implementation?

Methodology

To answer the guiding questions about prescribing patterns before and after implementation of, epidemiologists in the Office of Informatics and Analytics (OIA) used data from the Controlled Substance Monitoring Database (CSMD) to analyze prescribing trends, and TN death certificate data to examine overdose deaths. The CSMD includes information about nearly all opioid prescriptions dispensed in the state of Tennessee, and it is the primary source of data used throughout this report. OIA epidemiologists created a static dataset for the primary analyses for this report that included all opioid prescriptions written from January 1, 2016 to December 31, 2020. This dataset provides a common frame of reference for all analyses and is not subject to changes that can occur in the data as new prescriptions are reported and old ones are updated. The timeframe of 2016 through 2020 was chosen to include the same amount of time before and after the law's initial implementation on July 1, 2018 (i.e., the data includes the two-and-a-half-year period before this date and the two-and-a-half-year period after this date).

Prescriptions written by veterinarians or for non-human animals are excluded, as are those written by out of state practitioners, because these groups are excluded from the provisions of the law. The dataset includes only opioid prescriptions. Prescriptions for methadone products FDA-indicated for MAT are not currently reported to the CSMD; however, methadone products indicated for the treatment of pain are included along with other opioid analgesics in this report. Additionally, the static dataset excludes prescriptions reported with zero quantity or days' supply or implausibly high values for quantity and days' supply to ensure that incorrectly reported data do not influence the results.

Two measures of opioid prescribing are prominent in this report due to the specific restrictions in the law: days' supply and Morphine Milligram Equivalents (MME). Days' supply is typically calculated by the pharmacy dispensing a drug based on the total number of doses and the prescriber's dosing instructions. A prescription for 60 pills with the instruction to the patient to take twice daily will be reported as a 30 day supply. Days' supply is based on the prescriber's instructions and may not be what the patient actually uses. The prescription may instruct the patient to take a drug as needed, but it will still be assigned a days' supply value based on the maximum recommended daily dosage.

MME is a standardized measure of the dosage of an opioid drug that allows for comparison between opioids of different strengths. For example, MME allows for direct comparison of tramadol, a relatively weak opioid, with hydrocodone, a much stronger opioid. Total MME for a prescription is calculated as the quantity of pills/doses in a prescription, multiplied by the strength of the opioid, multiplied by an MME conversion factor. The MME conversion factor is supplied to TDH by the Centers for Disease Control and Prevention and is based on the relative strength of each type of opioid. Daily MME is calculated by dividing the total MME by the days' supply of the prescription. For example, a prescription for 60 10mg hydrocodone pills taken twice daily would be 600 total MME and 20 daily MME (60 pills × 10mg × hydrocodone MME conversion factor of 1 = 600 total MME; 600 total MME ÷ 30 days' supply = 20 daily MME).

Tennessee death certificate data provides information on fatal overdoses and substances involved in those deaths. TDH sends cause of death data from death certificates to the National Center for Health Statistics (part of the Centers for Disease Control and Prevention) which assigns

standardized codes to the causes to allow for cause of death comparison across places and time. These codes include an underlying cause of death along with contributing causes of death, based on the cause of death written by the medical certifier of each death. Overdose deaths are identified when the underlying cause of death code indicates a drug poisoning (accidental, intentional, or undetermined). A death that involved drug intoxication but not an overdose–for instance a motor vehicle accident while under the influence of drugs–will not be counted as an overdose. *Opioid* overdose deaths are identified when the contributing cause of death codes indicate that opioid drugs, including prescription and illicit opioids, were involved in the overdose. Opioids may not be the only drug present in the overdose death, and in fact multiple drugs are involved in over half of opioid overdose deaths in TN. The coding system used for death only identifies broad classes of opioids and does not always allow epidemiologists to identify specific types. For example, hydrocodone and oxycodone both fall under the code for "natural and semi-synthetic opioids" which is often used as a proxy for all prescription opioids.

The TDH Office of Informatics and Analytics, which is responsible for public health surveillance of drug overdose and controlled substances, releases an annual report on these topics in March of each year. While most of the analyses presented here were created for this report, several plots, and tables from the 2021 annual report have been reused to illustrate key facts. These analyses used a different subset of the CSMD data that did not exclude out of state practitioners or veterinary prescriptions. These differences do not change the conclusions presented in this report. Figures derived from the annual report have been noted as such.

Impact of TN Together Prescribing Limitations

What impacts did prescribing limitations contained in Tenn. Code Ann. § 63-1-164 have on the days' supply and Morphine Milligram Equivalents of opioid prescriptions written after the law's implementation?

Changes in Days' Supply

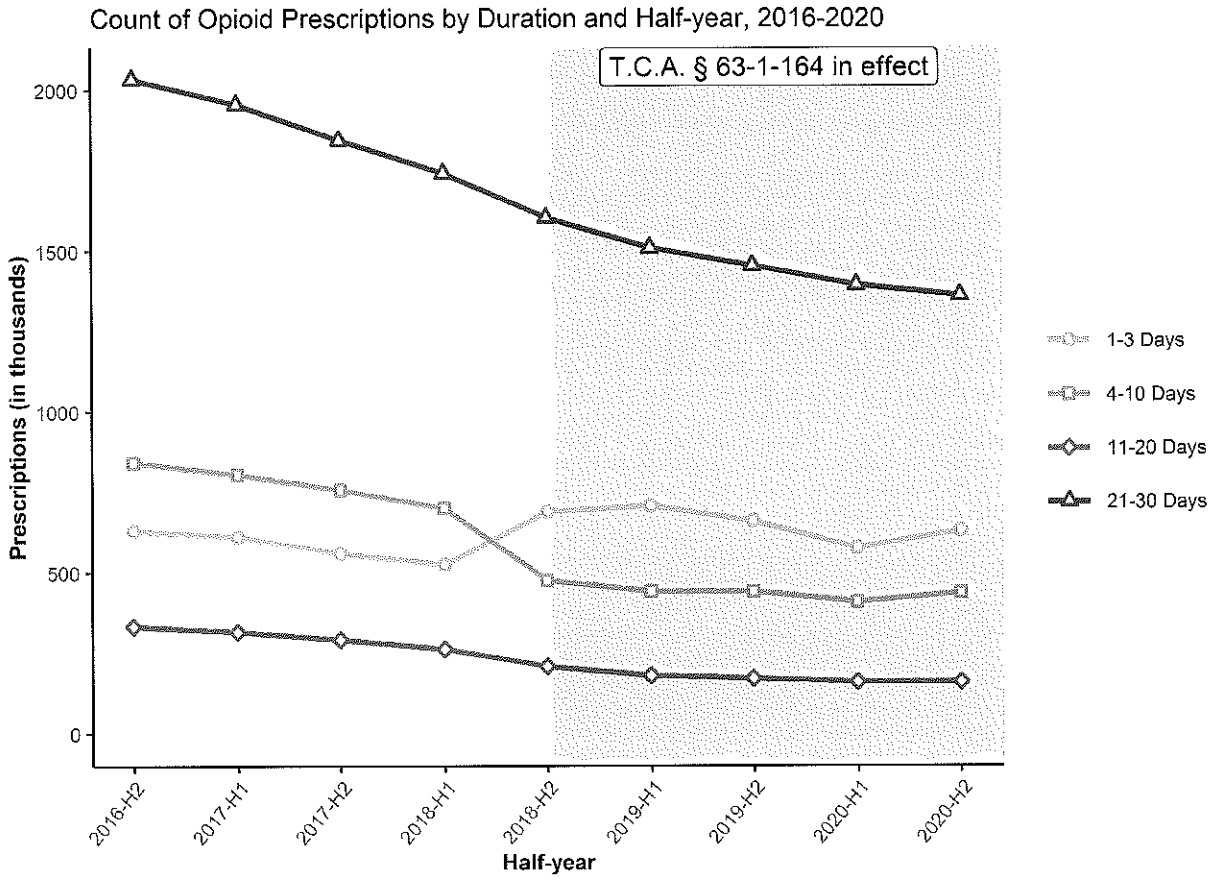
The most immediate impact of the Tenn. Code Ann. § 63-1-164 was the limitation of days' supply and MME for opioid prescriptions filled by non-exempt patients.

Figure 2 shows the number of opioid prescriptions written in each half-year period, categorized by the duration of the prescription. Opioid prescriptions in three of four categories decreased during this period. The most common duration across this period, both before and after the law changes, was 21-30 days, while the least common duration were prescriptions written between 11 and 20 days. The law's most evident impact on prescription duration occurred among those prescriptions filled for between 1 and 10 days' supply.

Prior to Tenn. Code Ann. § 63-1-164 taking effect, 4-10 day prescriptions were the second-most commonly filled duration prescriptions, followed by 1-3 day prescriptions.

When the law took effect, 1-3 day prescriptions became the second-most commonly filled duration prescriptions while 4-10 day prescriptions dropped to third-most common.

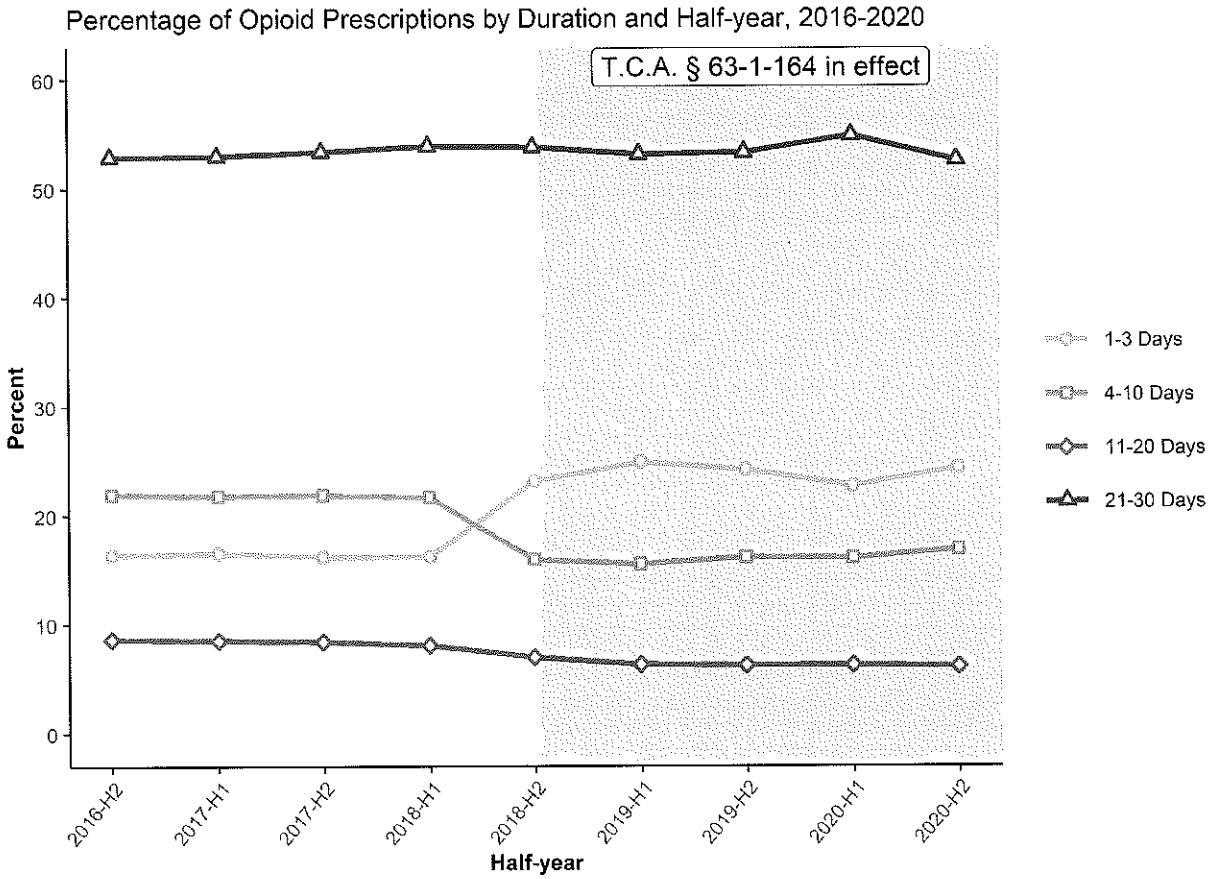
Figure 2



Looking at the absolute counts of prescriptions can be somewhat misleading as opioid prescriptions were declining across this period as a whole, regardless of duration. Figure 3 shows the relative amount of prescriptions filled for each duration. About 53% of all prescriptions filled in any given half-year are 21-30 days' supply.

The percentage of prescriptions in this longest-duration category did not change drastically when Tenn. Code Ann. § 63-1-164 went into effect. Prior to Tenn. Code Ann. § 63-1-164, prescriptions filled in the 1-3 days, 4-10 days, and 11-20 days ranges remained stable, accounting for about 16%, 22%, and 8% of prescriptions, respectively. Once the law took effect, however, the percent of 1-3 day prescriptions increased to approximately 24% of all opioid prescriptions, while the percent of 4-10 day prescriptions dropped to 16% and 11-20 day prescriptions dropped to 6%.

Figure 3



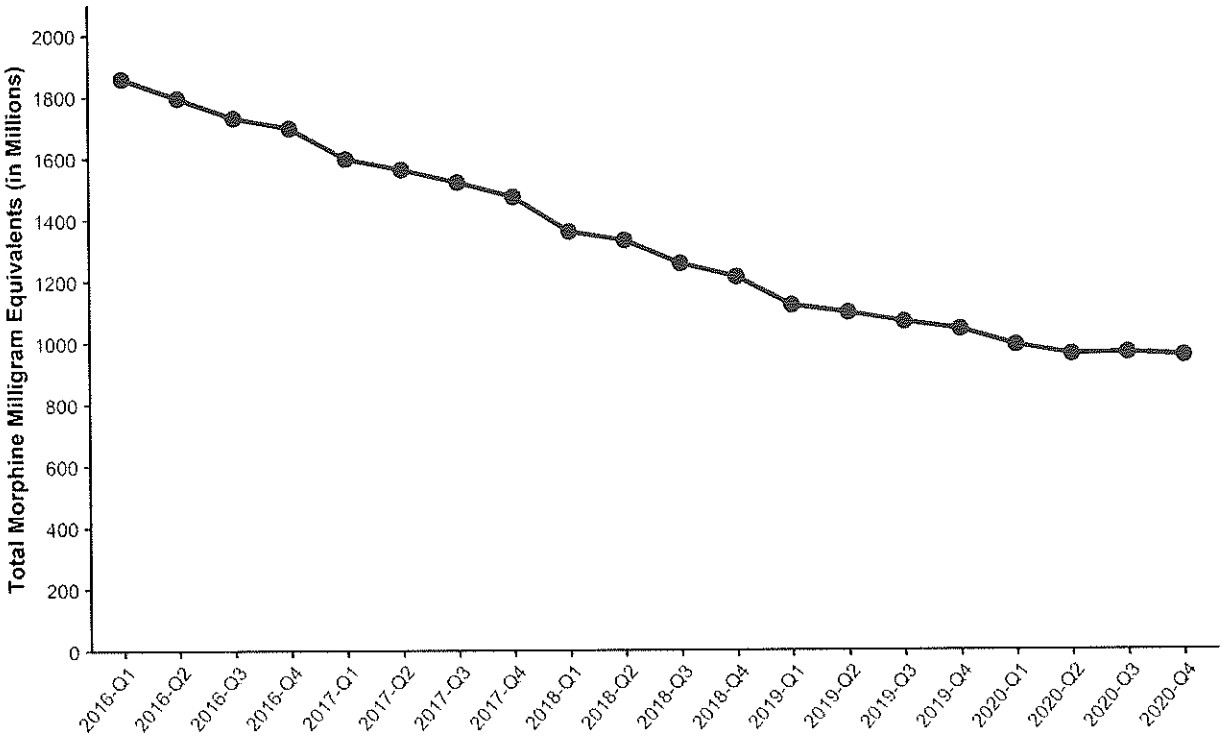
Tenn. Code Ann. § 63-1-164 had a clear and notable impact on opioid prescription durations overall. It does not appear to have created any drastic changes in the proportion of prescriptions of the longest duration, 21-30 days. The vast majority of prescriptions that fall into this category are written for 30 days, and as later sections of this report will show, many of them are written for patients who are on long-term opioid regimens.

Changes in MME

Morphine Milligram Equivalents are an important metric for understanding opioid prescription dosing, and they are also often a target of reductions to combat overprescribing. In Tennessee, total MME has fallen drastically over the five-year period from 2016 through 2020. Figure 4 illustrates the steady quarter-over-quarter decrease in total MME observed across this period.

Figure 4

Total Morphine Milligram Equivalents (MME) for Opioids for Pain in TN, 2016-2020



Source: Tennessee's Annual Overdose Report 2021 (https://www.tn.gov/TNODReport2021)

While total MME is a useful metric for understanding the total strength of opioids dispensed in the state, it does little to reflect the average dosage of individual prescriptions which can vary by drug type and days' supply. Additionally, PC1039 instituted restrictions on the total MME of each prescription written based on the days' supply and the medical necessity of the prescription. Initially, non-exempt 1-3 day prescriptions were limited to 180 total MME, a 10 day prescription was limited to 500 total MME, a 20 day prescription was limited to 850 total MME, and a 30 day prescription was limited to 1,200 total MME. Public Chapter 124 in 2019, effective July 1, 2019, removed the 20 day limit and replaced it with a 30 day, 1,200 total MME limit.

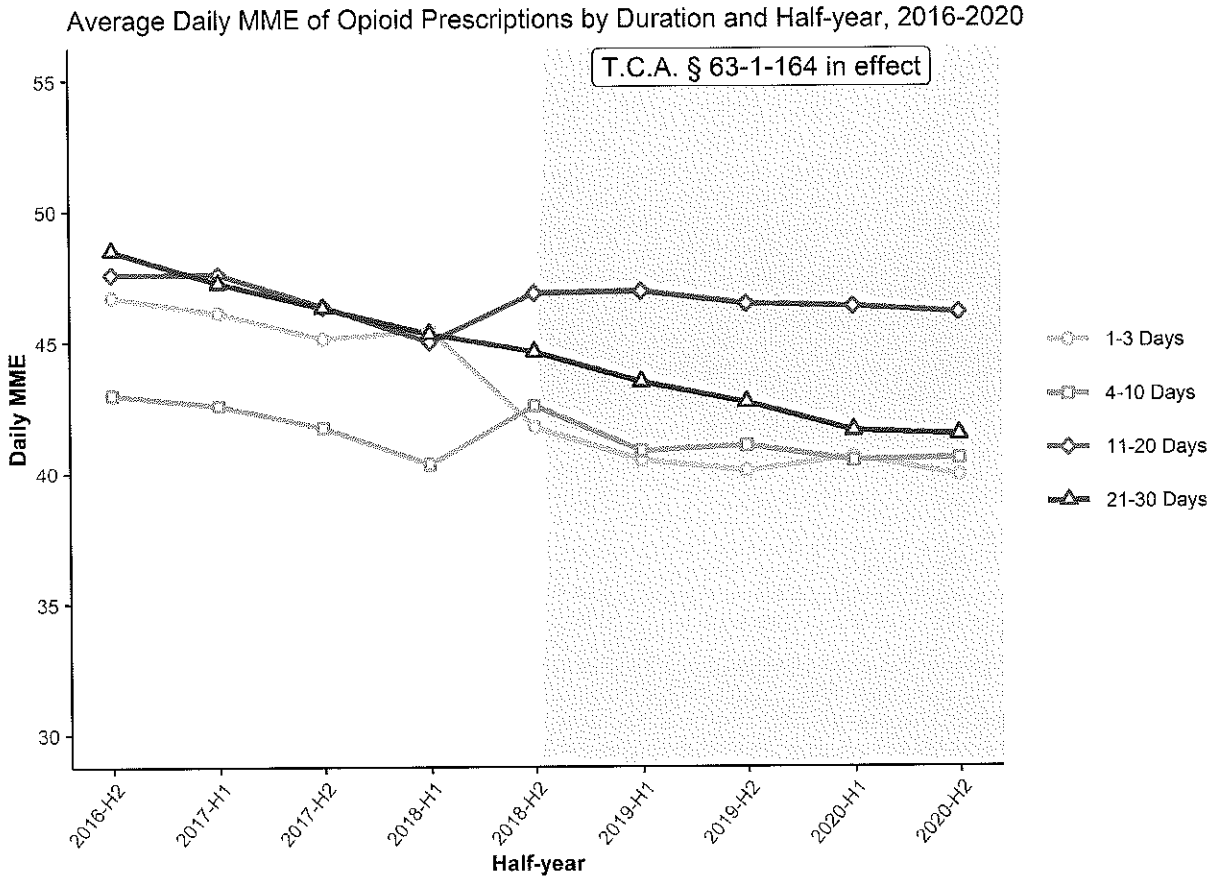
Figure 5 shows the average daily MME for prescriptions written in each half-year. Prior to the enactment of Tenn. Code Ann. § 63-1-164, the average daily MME for prescriptions of 11-20 days and 21-30 days was very similar: around 48 daily MME. The average daily MME for 1-3 day prescriptions was only slightly lower at about 47 daily MME. By the first half of 2018, the average daily MME had decreased but was nearly identical among these three durations at about 45 daily MME. Prescriptions of 4-10 days, however, were lower by 4-5 daily MME through this period.

When Tenn. Code Ann. § 63-1-164 was enacted, however, average daily MME shifted. For 11-20 day prescriptions, MME jumped up about 2 MME before settling slightly above the level they

were at just before the enactment of Tenn. Code Ann. § 63-1-164 (46 daily MME). Prescriptions of 21-30 days continued to decline in average daily MME without much perturbation and as of the last half of 2020, 21-30 day prescriptions averaged just over 41 daily MME.

Prescriptions of 1-3 days dropped suddenly from an average of about 45 daily MME to 42 in the first half-year after Tenn. Code Ann. § 63-1-164 took effect. Conversely, 4-10 day prescriptions increased from 40 daily MME just before enactment of Tenn. Code Ann. § 63-1-164 to 42 daily MME just after. In 2019 and 2020, daily MME for both 1-3 day and 4-10 day prescriptions looked very similar, both declining slightly to around 40 daily MME.

Figure 5



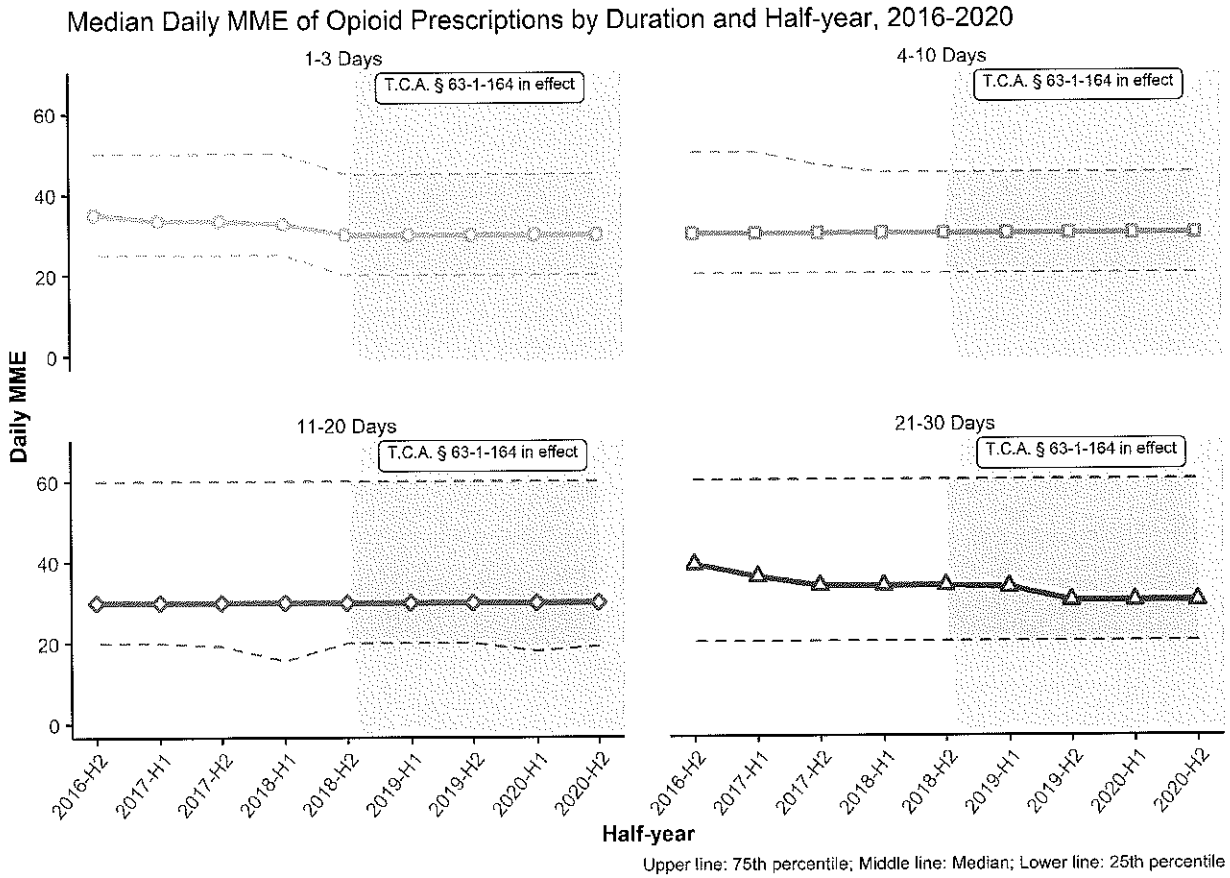
To better understand the "middle" of the data, Figure 6 shows the median values of daily MME for each group of prescriptions by duration. The median is the midpoint of the data, or the 50th percentile, and half the values fall above and half below this amount. Additionally, Figure 6 includes bands showing the 25th and 75th percentile, representing the values at which 25% and 75% of the data fall below that point, respectively.

Prescriptions of 1-3 days duration show a small but clear decrease from the period before enactment of Tenn. Code Ann. § 63-1-164 to the period after the law went into effect. The median for the 1-3 day group dropped from 35 daily MME in the second half of 2016 to 30 daily MME

for the entire period that Tenn. Code Ann. § 63-1-164 was in effect. Likewise, the 25th and 75th percentiles shifted a similar amount. For 4-10 day prescriptions, save for a small decrease in the 75th percentile, the distribution of daily MME was nearly the same before and after Tenn. Code Ann. § 63-1-164, with a constant median value of 30 daily MME.

The median value for 11-20 day prescriptions also stayed constant at 30 daily MME, but the 75th percentile was much higher, at 60 daily MME. Finally, the median for 21-30 day prescriptions shifted downward across the entire period (from 40 to 30 daily MME), with no obvious impact from the enactment of Tenn. Code Ann. § 63-1-164. The spread of the data in the 21-30 group remained unchanged across the entire period.

Figure 6



Changes in daily MME were most dramatic for shorter duration opioid prescriptions. While the TN Together laws allow for higher daily MME values at shorter durations (i.e., 180 total MME over 3 days = 60 daily MME compared to 1,200 total MME over 30 days = 40 daily MME), it appears that TN prescribers have tended toward even lower doses for these short prescriptions.

Conversely, average daily MME for 4-10 and 11-20 day prescriptions increased after Tenn. Code Ann. § 63-1-164 went into effect. However, there were fewer of these prescriptions overall (see

Figure 2) and the distribution of daily MME did not change substantially once the law went into effect (see Figure 6).

It is important to note that decreases in daily MME happened against the backdrop of decreasing total MME for opioid prescriptions overall, and it is difficult to definitively ascribe that overall downward trend to the enactment of Tenn. Code Ann. § 63-1-164. In particular, 21-30 day prescriptions tended toward lower daily MME both before *and* after the enactment of Tenn. Code Ann. § 63-1-164, and the law may have had little impact on this group of prescriptions. Later sections of this report turn to a closer look at the recipients of these long duration prescriptions: those being treated on long term opioid regimens, referred to patients with chronic pain. It is evident that Tenn. Code Ann. § 63-1-164 had an immediate and lasting impact on the duration of shorter prescriptions, with short 1-3 day prescriptions replacing many prescriptions that may have otherwise been written for 4-10 or 11-20 days.

How did long-term opioid use change for opioid-naïve/non-exempt patients?

One of the motivating factors behind the TN Together laws was to reduce the number of people who become long-term users of opioids. Scientific studies have shown that initial opioid prescriptions with higher doses and longer durations are associated with later long-term use (Shah A, 2017). This section examines the population of patients who are considered opioid-naïve at the time of their first prescription to determine how many became long term users in the subsequent year both before and after enactment of Tenn. Code Ann. § 63-1-164. To understand long-term use by initially opioid-naïve patients, it is helpful to understand trends in long-term use across all patients in TN.

Figure 7 shows the percentage of patients who received opioid prescriptions broken down by the total number of days of opioid prescriptions filled in a year. In other words, a patient who received two 3-day prescriptions in 2020 received a total of 6 days for the year and would be a part of the "1-7 days" group for that year. In 2016, about 48% of patients who received opioid prescriptions received a total of seven days or less of opioid prescriptions. In 2019 and 2020, the percentage increased to nearly 58%. At the same time, the percentage of patients who received opioid prescriptions receiving a total of between 8 and 270 days of opioid prescriptions decreased. The percentage of people receiving more than 270 days of opioid prescriptions increased slightly over this period, though it is important to note that the absolute number of patients in this category

decreased. This shift appears to have occurred in 2018, suggesting that the TN Together laws had the effect of decreasing the total number of days of prescriptions filled by most patients.

Figure 7

Percentage of Patients Filling Opioids for Pain by Number of Active Prescription Days in the Year, 2016-2020

Prescription Days	2016	2017	2018	2019	2020
1-7 days	47.9	49.3	53.0	57.9	57.6
8-30 days	21.8	21.0	18.4	15.5	15.8
31-90 days	8.8	8.4	7.5	6.2	6.2
91-180 days	5.3	5.0	4.7	4.2	4.0
181-270 days	4.0	3.8	3.8	3.4	3.3
> 270 days	12.2	12.4	12.6	12.8	13.2

Source: Tennessee's Annual Overdose Report 2021 (https://www.tn.gov/TNODReport2021)

The analysis above does not provide information on long-term opioid prescriptions by opioid-naïve patients. The remainder of this section examines these patients in-depth. For the following analyses, a patient is defined as opioid-naïve if they had not received an opioid prescription in the 365-day period before their initial prescription. This is a very stringent definition of opioid-naivety that was chosen to ensure maximum likelihood that the patient was truly opioid-naïve. Additionally, this long time period ensures that the patients would not fall under any long-term use exemption under the TN Together laws at the time of their initial opioid prescription.

Long-term opioid use is defined as receiving opioid prescriptions for at least 90 days in the 365-day period following the initial prescription. This definition was chosen to align with Tenn. Code Ann. § 63-1-164(e)(5) which exempts long-term opioid patients from the law's restrictions. Due to the limitations of the CSMD data, it is not possible to determine if a patient received opioids in another state or if they had received opioids in a hospital setting in the 365 days prior to or following the initial prescription. Because each patient requires a 365-day period both before and after their initial prescription, results are only presented for prescriptions filled in 2017 through 2019 (i.e., 2016 and 2020 data were used to determine eligibility for this cohort). Figure 8 shows the number of patients who were identified as opioid-naïve and long-term users under these definitions.

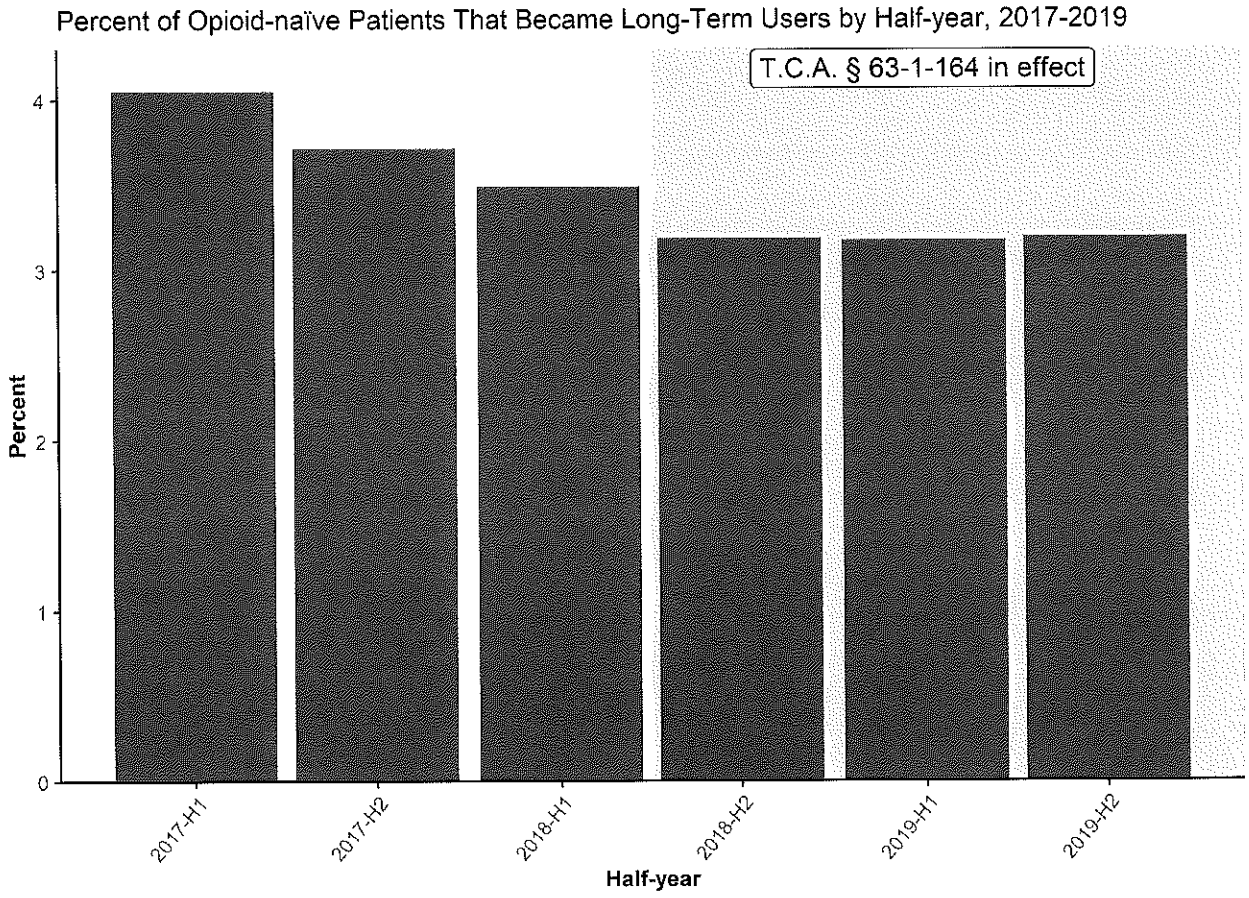
Figure 8

Year	Total Patients	Total Opioid-naïve	Became Long-term	Not Long-term
2017	1,725,095	1,016,581	39,489	977,092
2018	1,535,780	912,255	30,457	881,798
2019	1,396,619	866,950	27,572	839,378

Figure 9 below shows the percent of opioid-naïve patients who became long-term opioid users for each half-year period from 2017 through 2019. In the three half-year periods before Tenn. Code Ann. § 63-1-164 took effect, the percentage of patients who became long-term opioid users decreased from 4% to 3.5%. In the second half of 2018, when the law took effect, only 3.2% of opioid-naïve patients became long-term opioid users, and that percentage held steady through 2019.

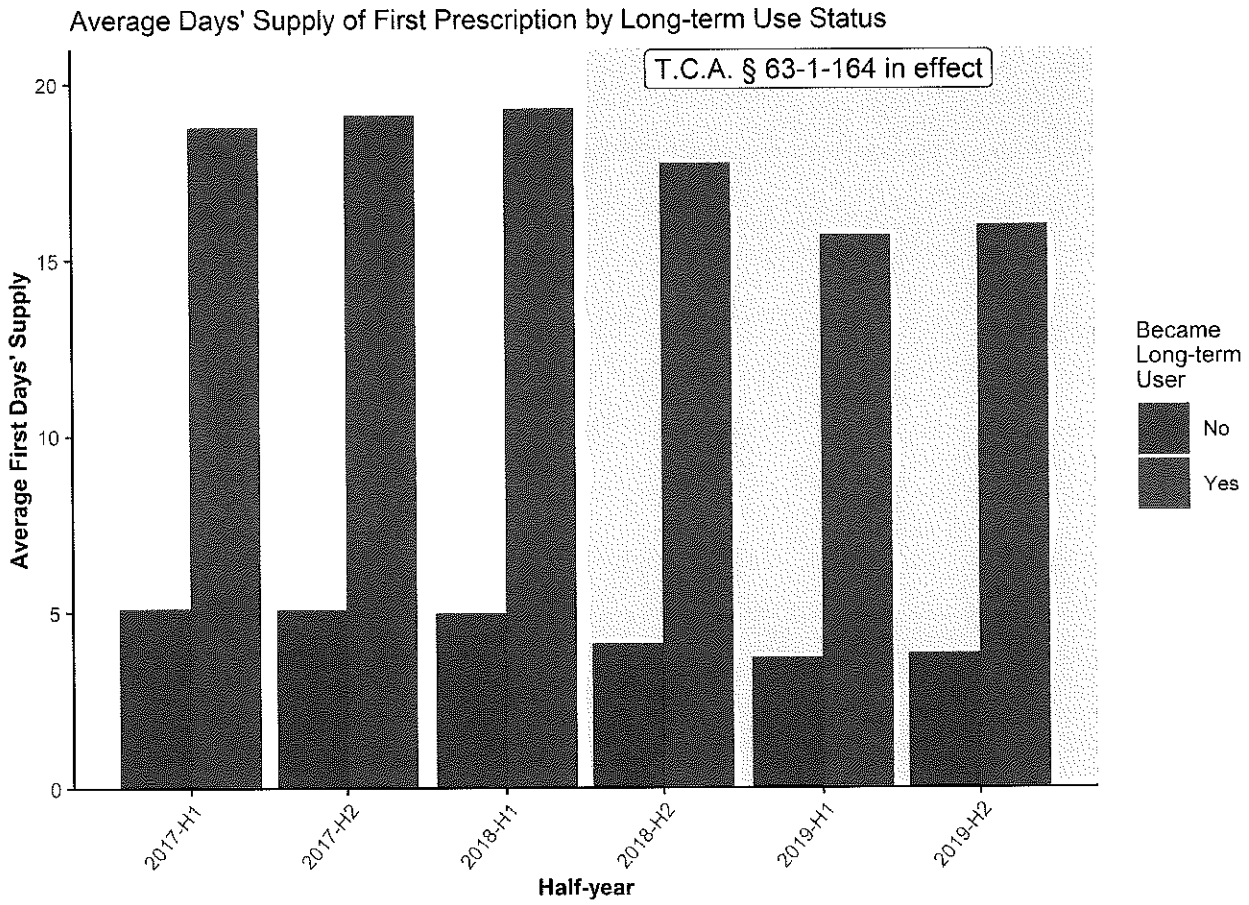
While this analysis offers an abbreviated look at the pre- and post-law period, it suggests that the decline in opioid-naïve patients becoming long-term users was much greater prior to enactment of Tenn. Code Ann. § 63-1-164 and leveled off after its enactment. The absolute number of patients becoming long-term users, however, continued to drop.

Figure 9



To better understand the characteristics of the initial prescriptions between the group of patients who became long-term users and those who did not, average days' supply and average daily MME at the initial opioid prescription was calculated for each group. Patients who became long-term opioid users had an initial prescription about two weeks longer than those who did not both before and after the enactment of PC1039 (see Figure 10). After the law went into effect, both groups had shorter initial prescriptions on average. The decrease in average days' supply was much larger for the group that went on to long-term opioid use (nearly 3 days) compared to those who did not (about one day shorter). There were no major changes for average daily MME at first prescription for these two groups.

Figure 10



Counter-intuitively, average daily MME of initial prescriptions was higher for those who did not become long-term opioid users compared to those who did (see Figure 11). There was little change for the long-term user group across this period (averaging about 32 daily MME), while the non-long-term group had lower average daily MME in each subsequent half-year period (decreasing from 38 to 34 daily MME). Despite having lower daily MME at initial prescription, the long-term group had higher average daily MME for all subsequent prescriptions (see Figure 12). Long-term opioid users averaged about 39 daily MME across all prescriptions while the non-long-term group dropped from about 39 to 35 daily MME across the period.

Figure 11

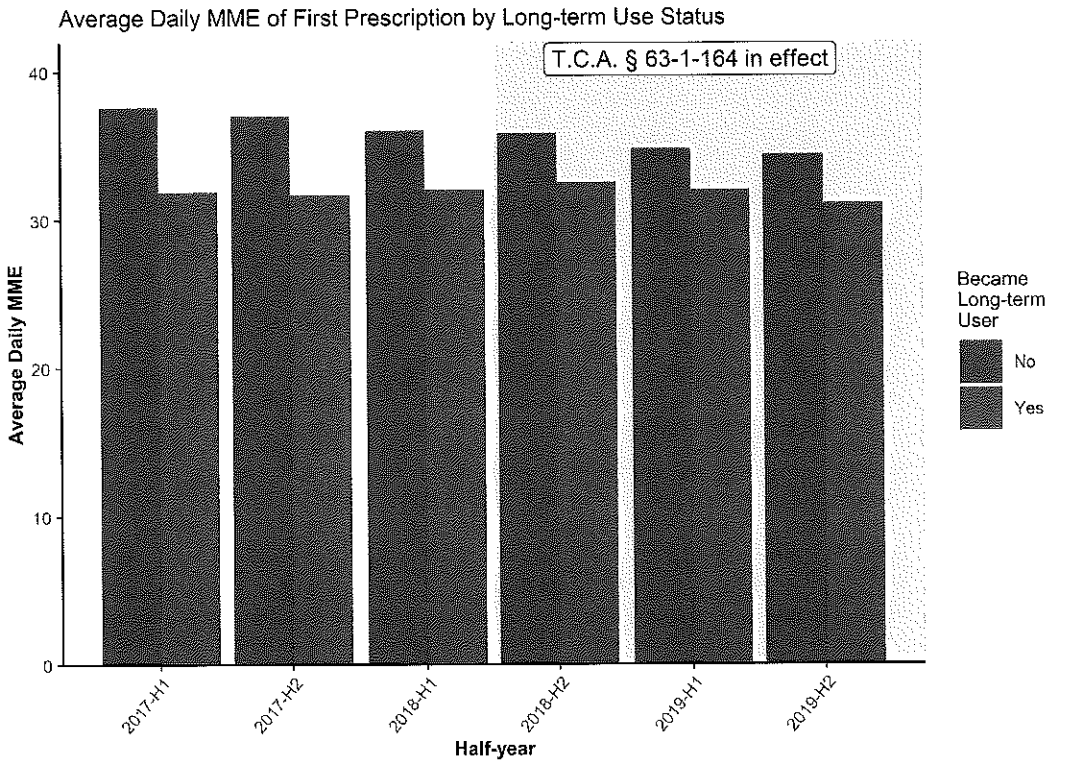
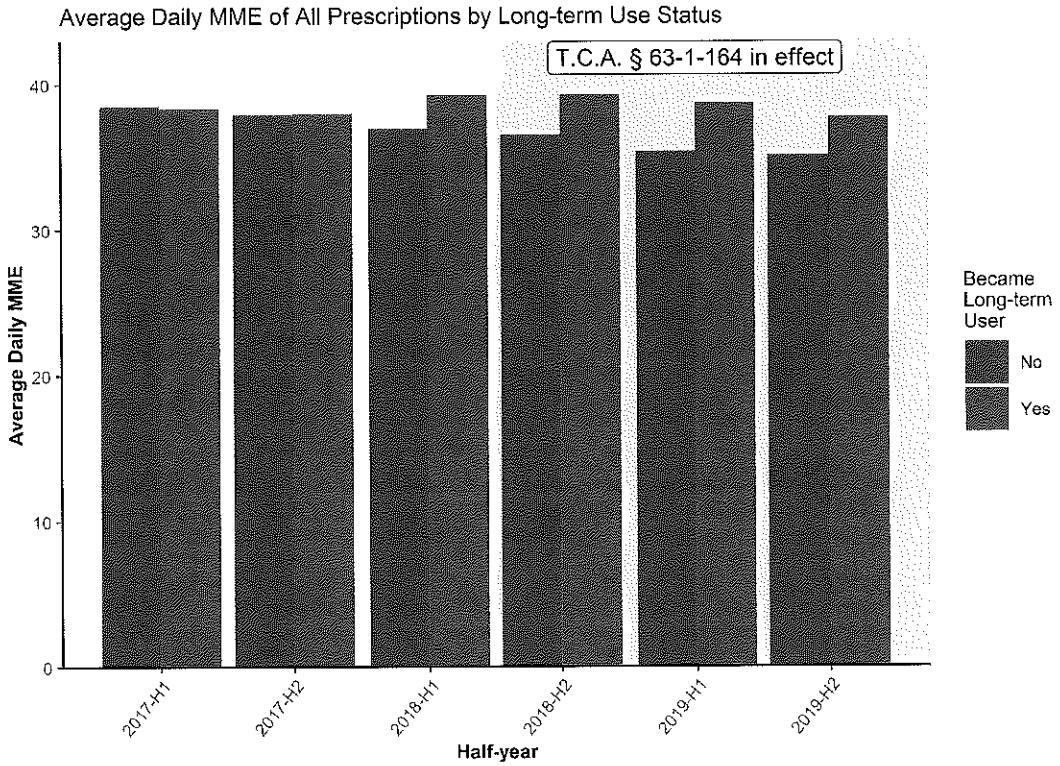


Figure 12



Did prescribing patters change for the population of patients with chronic pain who were specifically carved out by the law?

While the previous section focused on characteristics of long-term opioid users, it excluded patients who were already long-term users at the time Tenn. Code Ann. § 63-1-164 went into effect. Tenn. Code Ann. § 63-1-164 carved out a specific exemption from prescribing limits for "patients who have been treated with an opioid daily for ninety (90) days or more during the three hundred sixty-five (365) days prior to April 15, 2018." The intent of the law was not to prevent access to opioids to patients who had a medically necessary reason to use them. This exemption was one attempt to ensure that current long-term opioid users would not lose access to existing treatment.

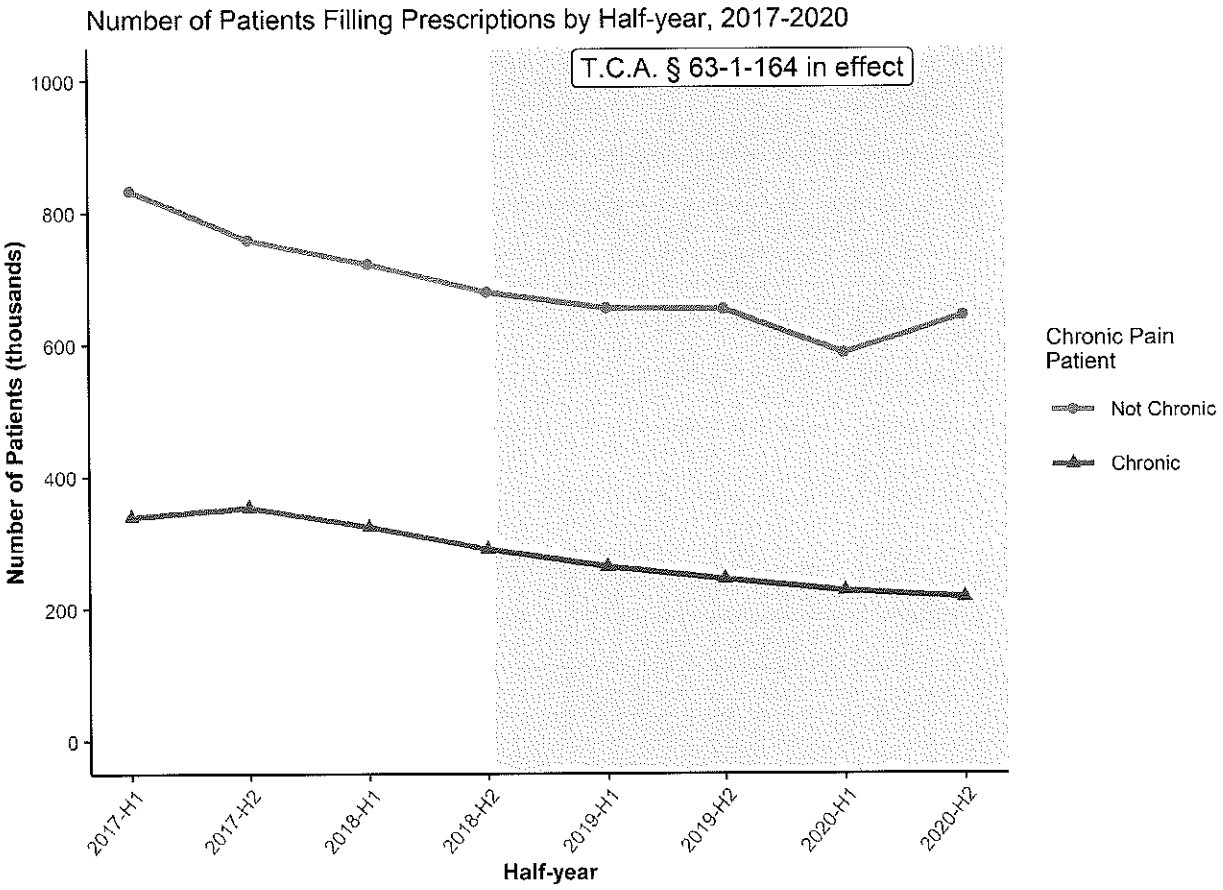
Because the law offers a number of possible medical exemptions, it is difficult to isolate those treated for chronic pain using CSMD data alone. The (e)(5) carve-out had the added benefit of creating a group of exempt patients who would be relatively easy to identify in the data available to the state. By examining this group, it is possible to determine if the enactment of Tenn. Code Ann. § 63-1-164 affected the accessibility of opioid therapy to these patients.

For the following analysis, the carve-out group is referred to as "patients with chronic pain." Though this description may not apply to all patients in this group, this terminology helps distinguish them from the group of long-term users examined in the previous section. These existing patients with chronic pain were identified by following a strict interpretation of the (e)(5) carve-out. Any patient with at least 90 calendar days of active opioid prescriptions in the 365 days before April 15, 2018 was included in the chronic pain patient group. Prescription days were not necessarily contiguous during this period, and overlapping opioid prescriptions were only counted once per day. In the figures below, the chronic pain patient group is compared to all other patients, regardless of their eventual status as a long-term user.

Approximately 357,000 patients were identified as patients with chronic pain according to the (e)(5) carve-out. Figure 13 shows the number of patients in this group that filled a prescription in each half-year, compared to all other patients. The carve-out group represented between 25-32% of all patients in any given half-year. The total number of patients in this group declined over time to approximately 216,000 patients in the second half of 2016. Some decline in the number of patients filling prescription in this group is expected as people cease opioid treatment, move out of state, or die.

Notably, there is no sudden major decrease among the patients with chronic pain immediately after Tenn. Code Ann. § 63-1-164 went into effect. (Note that the sudden dip among the non-chronic group in the first half of 2020 is related to the COVID-19 pandemic and is discussed in the COVID-19 section later in the report.)

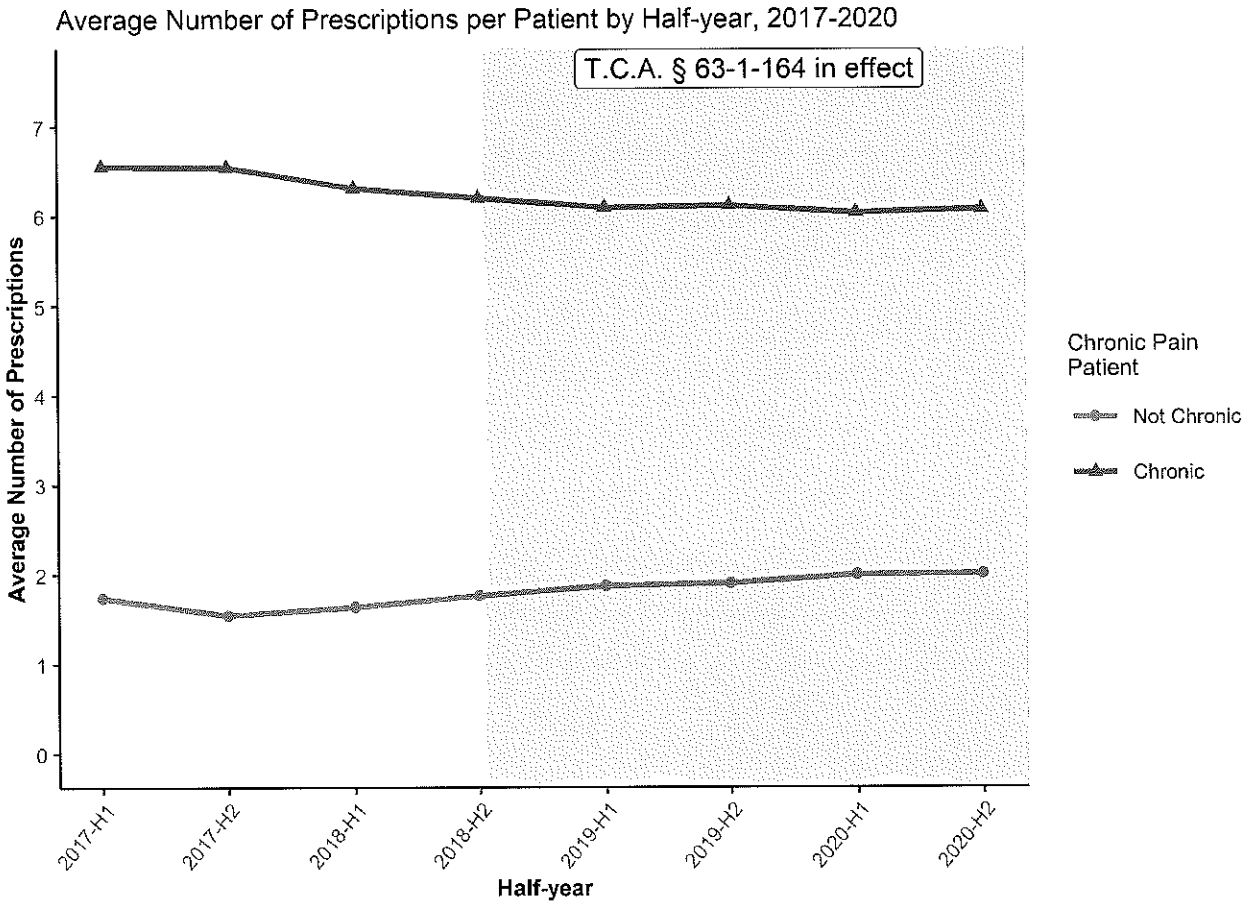
Figure 13



The number of patients with chronic pain may be misleading because a patient is counted if they filled any opioid prescription in a given half-year period, regardless of the amount or strength. Figure 14 shows the average number of opioid prescriptions to each patient with chronic pain by half year. Patients in this group averaged just over 6 prescriptions per half-year period, or about one every 30 days.

This number decreased only slightly across the period examined, from 6.6 in the first half of 2017 to 6.1 in the second half of 2020. The non-chronic group experienced a slight increase in the average number of prescriptions filled, from 1.7 in the first half of 2017 to 2 in the second half of 2020. This increase, though minor, may be related to shorter duration prescriptions and partial fills required under Tenn. Code Ann. § 63-1-164.

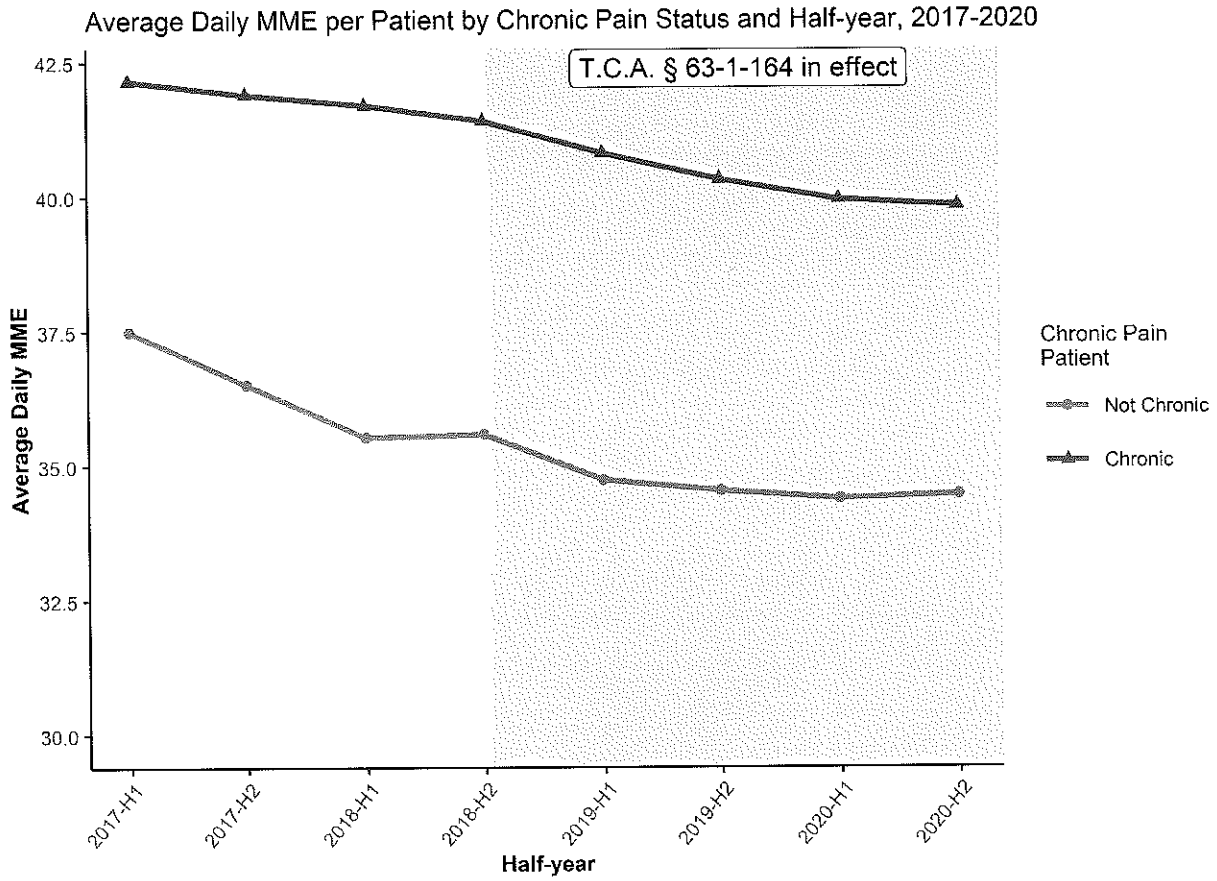
Figure 14



Total dosage for patients with chronic pain decreased at a slightly higher rate after Tenn. Code Ann. § 63-1-164 went into effect than before (see Figure 15). From the first half of 2017 to the second half of 2018, average daily MME for patients with chronic pain decreased just under 2%. From the second half of 2018 to the second half of 2020, average daily MME decreased about 4%. In absolute terms, these changes were small, only about 2 daily MME overall.

It is possible that Tenn. Code Ann. § 63-1-164 affected dosage among this exempt population, but these changes may also have been the result of the more general trend toward lower MME opioid prescribing. Patients without chronic pain experienced a much steeper decline that leveled off after Tenn. Code Ann. § 63-1-164 went into effect.

Figure 15



What types of justifications were recorded for prescriptions that were reported as exempt?

For opioid prescriptions that are exempt from the 3-day, 180 total MME restriction, Tenn. Code Ann. § 63-1-164 requires the submission of an International Classification of Diseases, Tenth Revision, Clinical Modification code (ICD-10-CM code; also referred to as "ICD-10 code" in the law). The ICD-10-CM codes were required to be submitted to the CSMD beginning January 1, 2019. These codes provide some information about the types of exemptions that are most common for opioid prescriptions in Tennessee.

Upon review of the data, it was determined that many ICD-10-CM codes were submitted in a nonstandard format, making a thorough description of exemptions difficult. In this section, only the higher order categories of ICD-10-CM codes, representing systems of diseases or encounter types, are presented. For this analysis, only opioid prescriptions of greater than three days were included. Unlike the previous sections, buprenorphine prescriptions for medication-assisted treatment were included because these prescriptions are also required to be accompanied by an ICD-10-CM code. Only a very small proportion of opioid prescriptions in 2018 had ICD-10-CM codes reported, so the results presented include only prescriptions written in 2019 and 2020.

The results of the ICD-10-CM code analysis are presented in Figure 16. The most common types of ICD-10-CM code reported were those pertaining to conditions of the musculoskeletal system and connective tissue (ICD-10-CM codes beginning with M00 through M99). These represent over 40% of all opioid prescriptions greater than three days. The second most common codes reported fell in the mental and behavioral disorders category (F01-F99). These "F codes" were reported for the vast majority of buprenorphine prescriptions. The third most common category included conditions of the nervous system (G00-G99). All other categories made up less than 5% of opioid prescriptions, each. In 2019, 23.8% of all opioid prescriptions greater than three days had no ICD-10-CM code reported, and this percentage dropped to 17.6% in 2020.

Figure 16

ICD-10-CM Code Categories Reported for All Opioid Prescriptions Greater Than Three Days, 2019-2020

	2019		2020	
ICD-10-CM Code Category	Percent	Count	Percent	Count
Musculoskeletal and Connective Tissue (M00-M99)	40.1	1,996,570	42.9	2,033,473
Mental and Behavioral Disorders (F01-F99)	11.3	563,951	14.3	679,591
Nervous System (G00-G99)	12.5	620,832	12.5	594,642
Factors Influencing Health Status and Contact with Health Services (Z00-Z99)	2.3	114,333	2.4	112,219
Neoplasms (C00-D49)	1.7	84,387	2.0	95,545
Injury, Poisoning, Certain Other Consequences of External Causes (S00-T88)	1.5	74,818	1.9	89,227
Symptoms, Signs and Abnormal Clinical and Lab Findings (R00-R99)	1.2	62,368	1.4	68,619
Other*	5.5	273,219	5.0	238,037
No Code Reported	23.8	1,182,633	17.6	833,337

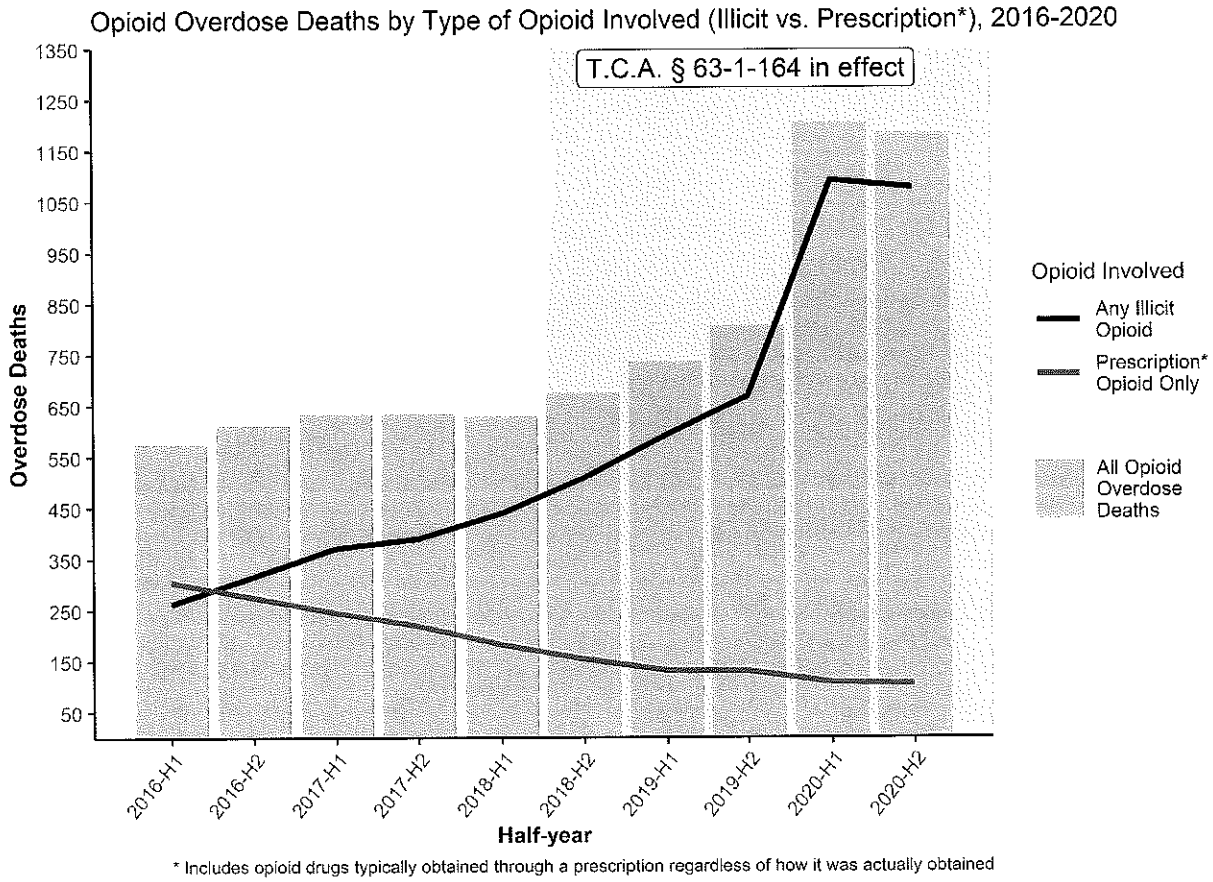
* Code categories making up less than 1% of all prescriptions were combined into the 'Other' category.

What changes were observed in overdose deaths involving prescription opioids before and after the law's implementation?

One of the most important long-term goals of efforts to limit the number of new opioid users and the availability of opioid drugs in Tennessee is to reduce the number of opioid overdose deaths in the state. Overdose deaths are often a lagging indicator of substance use, however. Any fundamental change in substance use in Tennessee, such as the availability of prescription or illicit drugs, is not likely to have major effects on overdose deaths in the near term. It is difficult to say with certainty what influence the enactment of the TN Together laws may have had on overdose deaths. This section describes how opioid overdoses involving prescription opioids have changed during the period before and after Tenn. Code Ann. § 63-1-164 went into effect.

As Figure 17 shows, opioid overdose deaths have been on the increase from 2016 to 2020, but the types of opioids involved have changed drastically. In this figure, opioid overdose deaths have been split into two categories, one that includes deaths involving *any* illicit opioid, and one that includes deaths in which the only opioid was an opioid typically obtained through a prescription. While prescription opioid-only deaths made up more than half of opioid overdose deaths in the first half of 2016, the number of deaths in this category declined considerably. By the end of 2020, about 10% of opioid overdose deaths involved prescription opioids only, and the rest involved illicit opioids.

Figure 17



Opioid overdose deaths began to rise more sharply after Tenn. Code Ann. § 63-1-164 went into effect. As mentioned previously, overdose deaths tend to be a lagging indicator of substance use. Prescription opioid-only overdose deaths were on the decline long before Tenn. Code Ann. § 63-1-164 was enacted, while simultaneously, illicit opioid overdose deaths were on a steady increase. The introduction and fast spread of illicit fentanyl and its analogs throughout Tennessee have caused opioid overdose deaths to increase rapidly across this five-year period in ways that are hard to predict. Factors outside the law, such as the availability of illicit drugs or accessible treatment options, can influence deaths. In 2020, overdose deaths, which were already on the rise, increased sharply as a corollary effect of the COVID-19 pandemic.

It should be noted that for the above analysis, prescription opioids are considered "natural and semi-synthetic opioids" according to the ICD-10 cause of death coding scheme typically used to define drug overdose deaths. This category of opioids includes drugs like hydrocodone and oxycodone and excludes heroin and synthetic opioids like fentanyl and tramadol. While these types of opioids are *typically* obtained through a prescription, information about how the drugs were obtained is not immediately available in the death data. To better understand prescription opioid trends in the period before opioid overdose deaths, TDH routinely links CSMD data with death data to determine which overdose decedents had prescriptions in the months before their death. The results of the most recent analyses are presented in Figure 18.

Figure 18

Percent of decedents[a] who filled a prescription for an opioid in the CSMD in the 60 days prior to death, 2016-2020

Overdose Death Type	2016	2017	2018	2019	2020
All Drug	40	35	28	23	19
All Opioid	42	38	29	24	19
Prescription Opioid[b]	52	52	42	37	35
Heroin	27	23	22	18	18
Fentanyl	28	24	19	19	15

[a] Total overdose decedents, 2016-2020 = 10,346; Decedents linked to CSMD = 8,979

[b] Includes deaths involving a "natural or semi-synthetic opioid" according to ICD-10 cause of death coding, regardless of how the drug(s) was actually obtained.

Source: Tennessee's Annual Overdose Report 2021 (https://www.tn.gov/TNODReport2021)

The values in the table above represent the percentages of *all* overdose decedents who overdosed from the opioid type listed under "Overdose Death Type" who had an opioid prescription in the CSMD in the 60 days prior to their death. Approximately 87% of all drug overdose decedents

between 2016 and 2020 were linked to a patient record in the CSMD. Unlinked decedents are included in these calculations as well.

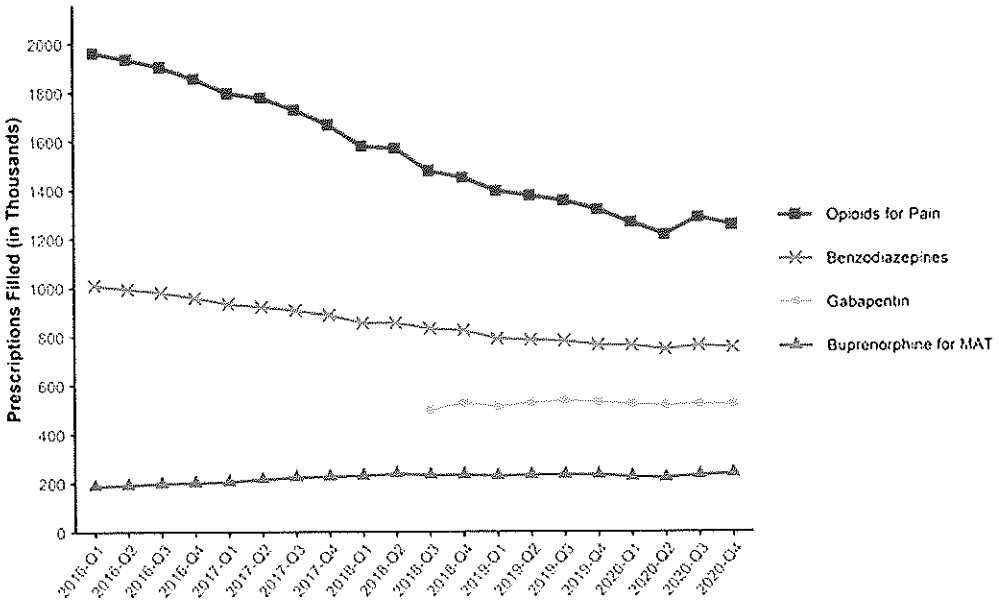
Over the period from 2016 to 2020, there has been a steady decline in the percentage of patients who died with an opioid prescription in the 60-day period before their death. This decreasing trend occurred regardless of the type of opioids involved in the death. Tennesseans who died of an overdose involving a prescription opioid were the group most likely to have filled an opioid prescription before their death. Like the other overdose death types, the percentage among this group dropped from 52% in 2016 to 35% in 2020. These results do not suggest an association between overdose decedents with recent prescriptions and the Tenn. Code Ann. § 63-1-164 effective period.

COVID-19 Pandemic-Associated Impacts on Prescribing

Figure 19 shows quarterly counts of controlled substance prescriptions filled by type of drug. There was a sharp decrease in the number of opioid prescriptions filled in Q2 of 2020, followed by a rebound in Q3 2020 that corresponds with the timing of COVID-19-related restrictions on activities, including halting elective surgeries in hospitals. Figure 20 shows quarterly counts of just opioid prescriptions for pain by days' supply. Again, the decrease and rebound between Q2 and Q3 2020 is apparent, but it occurs almost exclusively among the 1-3 and 4-10 day prescriptions. Similar trends are shown across the first and second half of 2020 in Figure 2. Figure 3 similarly showed that the percentage of longer duration opioid prescriptions increased in the first half of 2020 while the percentage of 1-3 day prescriptions decreased. These trends suggests that Tennesseans did not fill as many opioid prescriptions for acute or emergency needs during a period when elective procedures were halted, and emergency room visits dropped steeply. The rebound in Q3 2020 may be related to rescheduled procedures and the sudden increase in activity as COVID-19 restrictions were eased in the Fall. Conversely, patients with chronic pain did not appear to have difficulty filling prescriptions during this time.

Figure 19

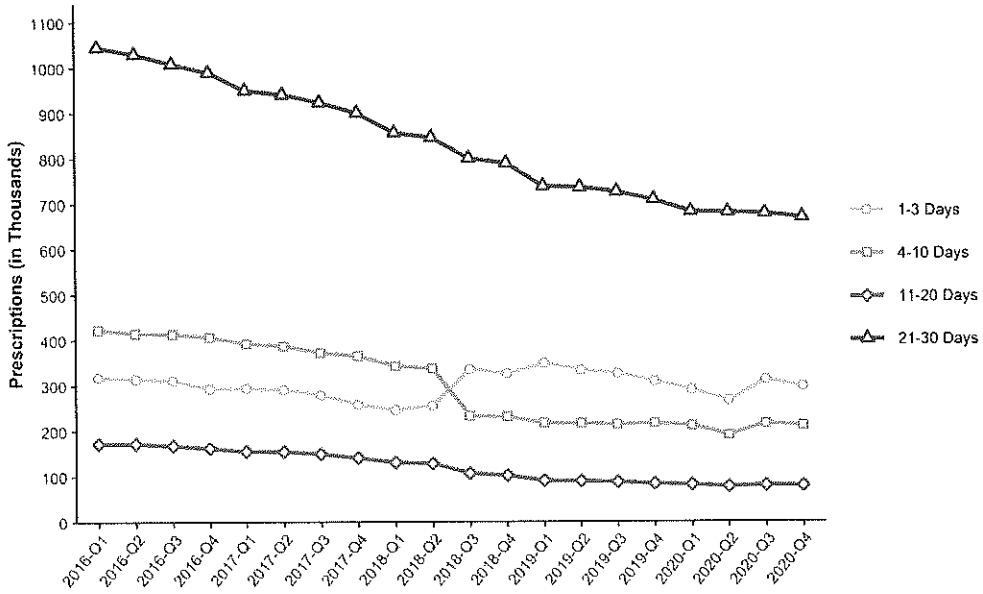
Number of Controlled Substance Prescriptions Filled by Selected Drug Class, 2016-2020



Source: Tennessee's Annual Overdose Report 2021 (https://www.tn.gov/TNODReport2021)

Figure 20

Number of Opioid for Pain Prescriptions by Days' Supply, 2016-2020



Source: Tennessee's Annual Overdose Report 2021 (https://www.tn.gov/TNODReport2021)

Because of the effects of the COVID-19 pandemic on healthcare and substance use, 2020 was anomalous compared to preceding years. Prescriptions dipped and total overdoses soared as the patterns of pre-pandemic daily life were disrupted for most Tennesseans. Some of these effects are lingering into 2021, and it remains to be seen if there will be a return to pre-pandemic levels or if 2020 marked a longer-term shift in illicit and prescription opioid use.

It should be noted that the Department does not have the ability to collect data related to the unlawful diversion of opioids due to the absence of a reporting requirement by law enforcement agencies.

Limitations of this Report

This report presents a largely descriptive set of analyses on key topics that were deemed important to investigate based on the intent of the TN Together laws. It does not include any attempts to model or predict what would have happened in the absence of the TN Together laws. Furthermore, this report does is not able to disentangle the effects of the TN Together laws compared to other factors that influenced prescribing during this period. These factors include, but are not limited to, increasing awareness among prescribers about the dangers of opioids, payer restrictions on opioid prescriptions (e.g., TennCare's Opioid Strategy), other laws that may have influenced prescribing (e.g., pain clinic restrictions), and the increasing availability of inexpensive illicit opioids (particularly fentanyl). This report suggests associations based on noted trends before and after the TN Together laws were enacted but cannot prove causation.

There are limitations of the data used in this report. The majority of the report relies on data from the CSMD. This data is relatively complete and accurate for all opioid prescriptions dispensed in the state, but errors can occur when data are submitted to the CSMD by dispensers. TDH does not have reason to believe these errors would substantially influence the conclusions made in this report, and the data used for the analyses exclude records that have implausible values. Additionally, the CSMD data used for this report does not include prescriptions written but never filled, nor does the data contain information about how patients actually use their prescriptions. All analyses assume prescriptions have been taken as directed.

Conclusion

The most immediate impact of the TN Together legislation was the limitation of days' supply and MME for opioid prescriptions. By and large, opioid prescriptions of all duration decreased during this period. The law's most evident impact on prescription duration occurred among those written for between 1 and 10 days' supply. Prior to TN Together taking effect, 4-10 day prescriptions were the second-most commonly filled duration prescriptions, followed by 1-3 day prescriptions. When the law took effect, 1-3 day prescriptions became the second-most commonly filled duration prescriptions while 4-10 day prescriptions dropped to third-most common. This analysis demonstrates that the decline in opioid-naïve patients becoming long-term users was much greater prior to enactment of TN Together and leveled off after its enactment.

Pursuant to Tenn. Code Ann. § 63-1-164, the Tennessee's Department of Health studied and analyzed the impact and effects of the restrictions and limitations of opioid prescriptions. In doing so, the department determined that an opioid-naïve person is now much less likely to receive a long duration prescription and somewhat less likely to become a long-term user. Patients with chronic pain do not appear to have suffered negative consequences on the whole, but that should not discount individual experiences and the possibility that some subpopulations have had bad experiences.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